

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOANNE NORIEGA, *on behalf of herself and all others
similarly situated*,

Plaintiff,

-v-

ABBOTT LABORATORIES,

Defendant.

23 Civ. 4014 (PAE)

Opinion & Order

PAUL A. ENGELMAYER, District Judge:

Plaintiff Joanne Noriega (“Noriega”) brings this action against defendant Abbott Laboratories (“Abbott”) under New York General Business Law (“NYGBL”) §§ 349 and 350 alleging deceptive acts or practices and false advertising in connection with Abbott’s product, PediaSure Grow and Gain (“PediaSure” or the “Grow and Gain drink”). *See* Dkt. 1 (“Compl.”) ¶¶ 62–80. Noriega, a grandmother, allegedly paid a premium in purchasing PediaSure for her grandson because of a statement on the product’s packaging that the nutritional supplement was “[c]linically proven to help kids grow.” *Id.* ¶¶ 44, 52. Noriega here claims that such a statement was materially misleading, as Abbott lacks reliable, clinical proof that PediaSure “helps kids grow,” at least in height. *Id.* ¶ 64.

Pending now is Abbott’s motion to dismiss the Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Dkt. 17. For the reasons that follow, the Court denies the motion.

I. Background

A. Factual Background

1. The Parties

Noriega is a grandmother living in the Bronx, New York. Compl. ¶ 9. Abbott is an Illinois health care-oriented corporation manufacturing, marketing, and selling products under the PediaSure brand name. Relevant here, these products include a PediaSure Grow and Gain line. *See id.* ¶¶ 11, 18. The PediaSure product at issue in that line is a “milk-based” drink that contains vitamins, minerals, sugar, flavoring, and dye. *See id.* ¶¶ 4, 38.

2. PediaSure’s Marketing Claim That the Grow and Gain Drink Is “Clinically Proven to Help Kids Grow”

Noriega’s Complaint challenges representations in PediaSure’s marketing that the Grow and Gain drink is “Clinically Proven to Help Kids Grow.” The packaging on the front of the drink includes a notation so stating. *See id.* ¶¶ 22–23. The packaging also contains an asterisk that appears as a superscript to the word “Proven.” It, in theory, directs a consumer to a statement on the labeling that reads, in smaller font: “Studied in children at risk of malnutrition.” *See id.* ¶¶ 22, 34. An example of this labeling is reproduced below:



Compl. ¶ 22. As this image reflects, the label on the Grow and Gain drink includes a cartoon giraffe next to, and exceeding the height of, a cartoon ruler. *Id.*; *see also id.* ¶ 23.

On the PediaSure website, Abbott lists six clinical studies as “references” supporting the statement in its packaging that the Grow and Gain drink is “clinically proven to help kids grow.” *See id.* ¶ 33.¹ These studies, also referenced in the Complaint, are as follows:

1. Pedro A. Alarcon, et al., *Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters*, 42 CLINICAL PEDIATRICS 209 (2003) [hereinafter “Alarcon Study”], Compl. ¶ 42 n.24.
2. M. Ramstack & R. Listernick, *Safety and Efficacy of a New Pediatric Enteral Product in the Young Child*, 15 JPEN 89 (1991) [hereinafter “Ramstack & Listernick Study”], Compl. ¶ 41 n.22.
3. D.S. Akram, et al., *PediaSure in the Treatment of Severe Malnutrition in Pakistani Children*, 50 JPMA 377 (2000) [hereinafter “Akram Study”], Compl. ¶ 41 n.21.
4. E. Morales, et al., *Dietary Management of Malnourished Children with a New Enteral Feeding*, 91 J. AM. DIET. ASSOC. 1233 (1991) [hereinafter “Morales Study”], Compl. ¶ 41 n.19.
5. Mauro Fisberg, et al., *Effect of Oral Nutritional Supplementation with or without Synbiotics on Sickness and Catch-up Growth in Preschool Children*, 17 INT’L PEDIATRICS 216 (2002) [hereinafter “Fisberg Study”], Compl. ¶ 41 n.20.
6. Dieu T. T. Huynh, et al., *Longitudinal Growth and Health Outcomes in Nutritionally At-Risk Children Who Received Long-Term Nutritional Intervention*, 28 J. HUM. NUTR. DIET 623 (2015) [hereinafter “Huynh Study”], Compl. ¶ 42 n.23.

¹ Available at <https://pediasure.com/nutrition-drinks-for-kids/grow-gain-nutrition-shakes>.

Noriega's Complaint cites three additional studies that, although financed by Abbott and undertaken by Abbott-affiliated researchers, are not listed as references on Abbott's PediaSure website for the claim on its packaging that the Grow and Gain drink is "[c]linically proven to help kids grow." Compl. ¶ 35. The Complaint alleges that these studies did not find evidence that PediaSure led to an increase in children's height-to-age or height-to-weight. These are:

1. Apurba K. Ghosh, et al., *Effect of Oral Nutritional Supplementation on Growth and Recurrent Upper Respiratory Tract Infections in Picky Eating Children at Nutritional Risk: A Randomized Controlled Trial*, 46 J. INT'L MED. RES. 2186 (2018) [hereinafter "Ghosh Study I"], Compl. ¶ 36 & n.14.
2. Apurba K. Ghosh, et al., *Continuation of Oral Nutritional Supplementation Supports Continued Growth In Nutritionally At-Risk Children with Picky Eating Behaviour: A Post-Intervention, Observational Follow-Up Study*, 46 J. INT'L MED. RES. 2615 (2018) [hereinafter "Ghosh Study II"], Compl. ¶ 37 n.16.
3. Deepti Khanna, et al., *Oral Nutritional Supplementation Improves Growth in Children at Malnutrition Risk and with Picky Eating Behaviors*, 13 NUTRIENTS 3590 (2021) [hereinafter "Khanna Study"], Compl. ¶ 39 n.18.

The Complaint also cites an article that it contends undermines the studies that Abbott's website references: Michelle Lampl, et al., *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*, 4 HEALTHCARE 84 (2016) [hereinafter "Lampl Study"], Compl. ¶ 44 n.26.

3. Noriega's Grandson's Experience with the Grow and Gain Drink

In or around January 2022, Noriega started buying PediaSure drinks for her eight-year-old grandson, for whom she is the primary caregiver. Compl. ¶ 48. Noriega's grandson, at the

time, was short for his age. *Id.* After viewing PediaSure’s online marketing and packaging touting the Grow and Gain drink as clinically proven to help kids grow, Noriega paid a premium to purchase it, understanding the product to have been clinically proven to help children like her grandson grow taller. *Id.* ¶¶ 48–49, 52. She forewent alternative nutritional supplements that did not make similar claims. *Id.* ¶ 53.

In February 2023, Noriega stopped purchasing PediaSure, because her grandson, despite ingesting two Grow and Gain Drinks per day, remained short for his age, and had become overweight. *Id.* ¶ 48.

B. Procedural History

On May 15, 2023, Noriega filed the complaint in this action, on behalf of herself and similarly situated New York purchasers of PediaSure’s Grow and Gain Drink. On May 18, 2023, the case was reassigned to this Court. That day, Noriega served Abbott. On July 24, 2023, Abbott timely filed a motion to dismiss the complaint, Dkt. 17, plus a memorandum of law and declaration in support, Dkts. 18 (“Abbott Br.”), 19 (“Brancato Decl.”). On July 25, 2023, this Court issued an order giving Noriega the choice either to amend her complaint or oppose the motion to dismiss. Dkt. 21. On August 23, 2023, Noriega filed a memorandum of law in opposition to the motion to dismiss. Dkt. 28 (“Noriega Br.”). On September 25, 2023, Abbott filed a reply. Dkt. 29 (“Abbott Reply”).

II. Applicable Legal Standards

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint is properly dismissed where,

as a matter of law, “the allegations in a complaint, however true, could not raise a claim of entitlement to relief. *Twombly*, 550 U.S. at 558. When resolving a motion to dismiss, the Court must assume all well-pleaded facts to be true, “drawing all reasonable inferences in favor of the plaintiff.” *Koch v. Christie’s Int’l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). That tenet, however, does not apply to legal conclusions. *See Iqbal*, 556 U.S. at 678. Pleadings that offer only “labels and conclusions” or “a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555.

Further, where a complaint incorporates by reference outside documents, such documents are otherwise integral to the complaint and relied upon by it, and/or outside documents are contained in a defendant’s motion papers and the plaintiff has knowledge or possession of those documents in initially crafting the complaint, the Court may consider these materials in deciding a Rule 12(b)(6) motion. *See Int’l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995); *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47–48 (2d Cir. 1991). And, where “a document relied on in the complaint contradicts allegations in the complaint, the document . . . control[s], and the court need not accept the allegations in the complaint as true.” *Mizel Roth IRA ex rel. Consol. Asset Funding 3 LP v. Unified Cap. Partners 3 LLC*, No. 19 Civ. 10712 (NRB), 2021 WL 1164439, at *1 (S.D.N.Y. Mar. 25, 2021).

III. Discussion

To state a claim under NYGBL § 349 or § 350, “a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.” *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (quoting *Koch v. Acker, Merrall & Condit Co.*, 944 N.Y.S.2d 452, 452 (2012)). “The New York Court of Appeals has adopted an objective definition of ‘misleading,’ under which the alleged act must be ‘likely to mislead a reasonable

consumer acting reasonably under the circumstances.’” *Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 126 (2d Cir. 2007) (quoting *Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 623 N.Y.S.2d 529, 533 (1995)). To determine whether a product’s labeling is misleading, courts view the allegedly misleading statement in the context of the label read as a whole. *See Colpitts v. Blue Diamond Growers*, 527 F. Supp. 3d 562, 581 (S.D.N.Y. 2021). And, “while it is possible for a court to decide this question as a matter of law, this inquiry is generally a question of fact not suited for resolution at the motion to dismiss stage[.]” *Duran v. Henkel of America, Inc.*, 450 F. Supp. 3d 337, 346 (S.D.N.Y. 2020) (citations omitted) (collecting cases).

In moving to dismiss, Abbott argues that Noriega’s Complaint does not plausibly allege that Abbott’s statement that the Grow and Gain drink is “clinically proven to help kids grow” is materially misleading.² Abbott emphasizes that the Complaint itself references studies listed on Abbott’s website that tend to show growth as a result of ingesting the drink. Abbott Br. at 5–8. In opposing dismissal, Noriega points to countervailing material cited in her Complaint: (1) other scientific studies, (2) articles, and (3) methodological and other criticisms of the studies Abbott’s website references. These, she argues, make plausible her claim that Abbott’s claim that it is “clinically proven” that the drink “helps kids grow” is materially misleading. Noriega Br. at 15–18 (citing Complaint ¶¶ 35–40).

The Court holds that Noriega’s Complaint pleads enough to plausibly state a claim under NYGBL §§ 349 and 350. This precludes pre-discovery dismissal.

Abbott’s central argument is that the clinical studies cited on its website support that PediaSure has been clinically proven to help kids grow, and therefore it is implausible to term

² Abbott does not contend that the Complaint implausibly pleads the first and third elements of violations of NYGBL §§ 349 and 350.

that claim materially misleading. Abbott Br. at 7–8. These studies, Abbott notes, found an increase in height and/or height-for-age percentiles among children who had ingested PediaSure. *Id.*; *see also* Alarcon Study at 216 (“In summary, gains in weight and height were higher . . . in subjects who received a nutritional supplement and nutrition counseling, compared with children who received nutrition counseling alone.”); Fisberg Study at 219 (finding that children given PediaSure “demonstrated an increase in height, weight, and weight/height ($p < 0.001$) as measured by increasing percentiles over time”); Huynh Study at 623–34 (“Height-for-age percentiles increased steadily over time and became significantly higher than baseline from week 24 onwards”). Abbott contends that these studies are enough to support its marketing claim about the existence of “clinical proof” of a growth impact to make the Complaint’s challenge to that claim implausible.

The existence of support for Abbott’s claim, however, is not the end of the inquiry. As Noriega’s Complaint alleges, there are strong, evidence-backed reasons to doubt Abbott’s claim including clinical studies that Noriega suggests may be as or more sound than those Abbott cites. The Complaint alleges that Abbott was privy to these critiques and evidence in 2022 and early 2023, when it made and Noriega claims to have acted upon its labelling claims. This evidence falls into three categories.

First, the Complaint makes methodological critiques of the studies on which Abbott claims to have based its label’s claim. *See* Compl. ¶ 42 (alleging that Alarcon Study did not sufficiently deal with potentially confounding variable of “catch-up growth”); *id.* (alleging that Huynh Study lacked control group); *id.* ¶ 41 (alleging that Fisberg study involved a substance different from PediaSure and did not study height regardless). On the Court’s review, these critiques cannot be put aside, on the pleadings, as implausible. In similar cases, critiques of the

reliability of studies that formed the basis of a label's claim that a product has been "clinically proven" to secure certain results have been held to plausibly support a Complaint's contention that that claim was misleading. *See, e.g., Hidalgo v. Johnson & Johnson Consumer Companies, Inc.*, 148 F. Supp. 3d 285, 297–98 (S.D.N.Y. 2015) (complaint stated § 349 claim that "clinically proven" representations were misleading where it alleged that manufacturer's studies had not tested the product in isolation, but instead tested a separate three-step routine); *Proctor & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (in Lanham Act false advertising case, complaint plausibly alleged ads were misleading where the tests to which they referred "were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited"); *cf. McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d 226, 250–51 (S.D.N.Y. 2005) (holding, on application for preliminary relief, a likelihood of success on the merits where challenger alleged that clinical studies on which advertisements claiming product's effectiveness were insufficiently reliable).

To be sure, Noriega's methodological critiques may or may not ultimately be shown to hit the mark.³ But on the Court's initial assessment they cannot be set aside, as Abbott urges, as

³ In finding the Complaint's § 349 and § 350 claims plausibly pled, the Court does not here rely on one critique it lodges: that it was methodologically improper for the studies supporting the label's "clinically proven" claim to be based on children suffering from malnutrition in foreign countries. Noriega contends that the nutritional experiences of such children materially differ from those of children in New York State. *See* Compl. ¶¶ 3–4; Noriega Br. at 15–16. Noriega contends that PediaSure's reliance on such studies makes its marketing misleading to New York consumers, because such "American children . . . are not 'at risk of malnutrition.'" Noriega Br. at 16. Although Noriega is at liberty to pursue such a theory in this litigation, the Court, in finding the Complaint's § 349 and § 350 claims plausibly pled, puts aside these dubiously sweeping generalizations about the nutritional experiences of American children. Relatedly, the Court here does not resolve the parties' dispute about whether Abbott's disclaimer in its asterisked footnote that PediaSure was "studied in children at risk for malnutrition" was sufficient to cure any problem created by the studies' reliance on foreign children; Abbott so argues, but Noriega claims that that disclaimer was too small and obscurely placed to alert a

facially insubstantial or implausible. *Cf.* Abbott Br. at 10–11. Some of the critiques derive from a published, peer-reviewed paper. *See* Lampl Study at 89. And although “identifying flaws in a scientific study does not necessarily make marketing statements based on such a study false or misleading,” *In re Riddell Concussion Reduction Litig.*, 121 F. Supp. 3d 402, 416 (D.N.J. 2015), at the motion-to-dismiss phase, it is not the Court’s province to look beneath a facially colorable methodological critique where doing so would require resolving factual disputes and/or making scientific assessments. *See, e.g., Sitt v. Nature’s Bounty, Inc.*, No. 15 Civ. 4199 (MKB), 2016 WL 5372794, at *10 (E.D.N.Y. Sept. 26, 2016) (“Factual disputes about whether the studies actually prove that [product] is ineffective, or whether there is mere scientific debate regarding the benefits of [product], cannot be resolved by the Court on a motion to dismiss.”); *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 461–62 (E.D.N.Y. 2013) (“Issues concerning the weight that should be given to [a] study cannot be resolved on a motion to dismiss.”); *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) (“Whether or not the studies support plaintiff’s proposition . . . is an issue of fact the Court cannot resolve on a motion to dismiss.”). In short, whether the studies on which Abbott relies are sound and support its label’s claim of clinical proof is fairly put issue by the Complaint and cannot be resolved on a motion to dismiss.⁴

reasonable consumer to the caveat. *See Mantikas v. Kellogg Co.*, 910 F.3d 633, 636–37 (2d Cir. 2018); *see also Henry v. Nissin Foods (U.S.A.) Co. Inc.*, No. 22 Civ. 363 (NGG) (RER), 2023 WL 2562214, at *7 (E.D.N.Y. Mar. 17, 2023) (“The ability of a disclaimer to cure a misrepresentation created elsewhere on a product’s packaging depends on the nature of such misrepresentation.”).

⁴ Warning that “every clinical study could be criticized in some way,” Abbott argues that denying a motion to dismiss on the basis of Noriega’s methodological critiques would mean that “plaintiffs could always survive a motion to dismiss in lawsuits challenging an advertising claim indicating clinical support merely by nitpicking a study’s methodology.” Abbott Br. at 10. At a conceptual level, Abbott’s point is well-taken. But Noriega’s Complaint here goes well beyond “nitpicking.” It anchors its § 349 and § 350 challenges to Abbott’s labeling claim on diverse sources that, viewed together, make its critique substantial, and plausibly pled.

Second, the Complaint cites published literature that takes issue with the methodologies of several of the studies on which the Abbott label's effectiveness claim relies. *See* Lampl Study at 89 (referencing and criticizing "five different studies referenced on a commercially-sponsored website," that website being Abbott's for PediaSure Grow and Gain); *id.* at 89 (criticizing ability of Alarcon Study and Fisberg Study to zero in on height gains given aspects of study design); *id.* (criticizing Morales Study for benchmark used to assess height and weight); *see, e.g., Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 543–44 (S.D.N.Y. 2013) (complaint plausibly stated a claim under New York consumer protection law where it cited to scientific studies tending to show that claims on product labeling were scientifically impossible); *Pearson v. Target Corp.*, No. 11 Civ. 7972 (JBZ), 2012 WL 7761986, at *2 (N.D. Ill. Nov. 9, 2012) (complaint pled viable claim under state law for deceptive acts and practices where it noted specific clinical studies and alleged how their results refuted the defendants' marketing claims).

Third, the Complaint cites three studies funded by Abbott itself which did *not* find a connection between PediaSure and growth in height. *See* Compl. ¶¶ 35–40. To be sure, the Complaint's characterization of these as having "conclusively demonstrate[d]" the falsity of Abbott's clinically proven claim, *id.* ¶ 40, appears overstated. But these studies do not support the claim on the PediaSure label. And the existence of studies contradicting the label's claim reinforce the plausibility of the Complaint's allegation that the label would mislead a reasonable consumer. *See, e.g., Quinn*, 958 F. Supp. 2d at 543–44; *Hughes*, 930 F. Supp. 2d at 461 (reference to scientific study refuting claim made by defendant sufficient to state a plausible claim of misrepresentation); *Sitt*, 2016 WL 5372794, at *10 ("Plaintiff's allegations are sufficient to state that Defendants' representations are materially misleading because she has . . . explained in detail her allegation that the scientific evidence shows that this representation is false.").

Abbott downplays these studies, claiming that methodological flaws in these studies led them not to find statistically significant increases in PediaSure users' height. Abbott Br. at 8–9. But that contention, too, cannot be resolved on a motion to dismiss; it is more properly assessed with the benefit of discovery. *See, e.g., Hughes*, 930 F. Supp. 2d at 461–62; *Sitt*, 2016 WL 5372794, at *10; *Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83, 97 (S.D.N.Y. 2021) (“Here, as in most cases, the question of whether Defendant’s labeling would prove misleading to the reasonable consumer is a question of fact that cannot be resolved on a motion to dismiss.”).

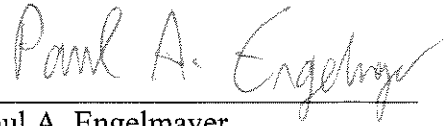
The Court accordingly finds that the Complaint’s allegations, taking into consideration the cognizable materials cited therein, plausibly plead that Abbott’s claim that its Grow and Gain drink was “[c]linically proven to help kids grow” was materially misleading to reasonable consumers, in violation of §§ 349 and 350. As Abbott does not challenge to the Complaint’s pleadings with respect to the other elements of these claims, the Court accordingly denies Abbott’s motion to dismiss.

CONCLUSION

For the foregoing reasons, the Court denies Abbott’s motion to dismiss in its entirety. The Clerk of Court is respectfully directed to terminate the motion pending at Docket 17.

By separate order, the Court will schedule an initial conference, at which it will put in place a case management plan providing for prompt discovery of Noriega’s claims.

SO ORDERED.

A handwritten signature in cursive script, reading "Paul A. Engelmayer". The signature is written in dark ink and is positioned above a horizontal line.

Paul A. Engelmayer
United States District Judge

Dated: February 2, 2024
New York, New York